Pharmacy

Prior Authorization Criteria for Cymbalta (duloxetine)

Background

The depression/non-opioid pain syndrome agents include a variety drug agents, including the selective serotonin re-uptake inhibitors (SSRIs), selective serotonin/norepinephrine reuptake inhibitors (SNRIs), serotonin antagonist reuptake inhibitors (SARIs), norepinephrine/dopamine reuptake inhibitors (NDRIs), alpha-2 receptor antagonists (A2RAs), serotonin partial agonist/reuptake inhibitors (SPARIs), the gamma-aminobutyric acid (GABA) analogs; and the tricyclic antidepressants (TCAs). The DOD Pharmacy and Therapeutics Committee reviewed the depression/non-opioid pain syndrome agents at its November 2011 meeting and recommended that step-therapy (prior authorization) criteria apply to **Cymbalta (duloxetine)**, Lyrica (pregabalin), Pristiq (desvenlafaxine) and Savella (milnaciprin).

What is Step Therapy?

Step therapy involves prescribing a safe, cost effective medication as the first step in treating a medical condition. The preferred medication is often a generic mediation that offers the best overall value in terms of safety, effectiveness, and cost. Non-preferred drugs are only prescribed if the generic is ineffective or poorly tolerated.

Cymbalta (duloxetine), Lyrica (pregabalin), Pristiq (desvenlafaxine) and Savella (milnaciprin) will only be approved for first time users after they have tried one of the preferred agents on the Department of Defense (DOD) Uniform Formulary. Beneficiaries who filled a prescription for any of these medications during the last 180 days will not be affected by step therapy requirements and won't have to switch medications.

Prior Authorization Criteria for Cymbalta (duloxetine)

All current and new users of **Cymbalta (duloxetine)** must meet one of the following criteria in order for Prior Authorization to be approved:

1. The patient has failed therapy with the formulary depression/non-opioid pain syndrome agents, which is not expected to occur with duloxetine (Cymbalta).
2. The patient has a contraindication to the formulary depression/non-opioid pain syndrome agents, which is not expected to occur with duloxetine (Cymbalta).
3. The patient has experienced adverse events with the formulary depression/non-opioid pain syndrome agents, which is not expected to occur with duloxetine (Cymbalta).
4. The patient has previously responded to duloxetine (Cymbalta) and changing to a formulary depression/non-opioid pain syndrome agent would incur unacceptable risk.

Criteria approved through the DOD P&T Committee process November 2011

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TRICARE Management Activity,
a component of the Military Health System
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Falls Church, VA 22041-3206

Prior Authorization Request Form for Cymbalta (duloxetine)

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To be completed and signed by the prescriber. To be used only for prescriptions which are to be filled through the Department of Defense (DoD) TRICARE pharmacy program (TPHARM). Express Scripts is the TPHARM contractor for DoD.

MAIL ORDER and RETAIL	• The provider may **call**: **1-866-684-4488** or the completed form may be **faxed** to: **1-866-684-4477** • The patient may attach the completed form to the prescription and **mail** it to: **Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954** or **email** the form only to: **TPharmPA@express-scripts.com**

Prior authorization criteria and a copy of this form are available at: http://pec.ha.osd.mil/forms_criteria.php. This prior authorization has no expiration date.

Step 1 **Please complete patient and physician information** (please print):

Patient Name: _____ Physician Name: _____

Address: _____ Address: _____

_____ _____

Sponsor ID # _____ Phone #: _____

Date of Birth: Secure Fax #:

Step 2 **Please complete the clinical assessment:**

1. What is the diagnosis?	□ Depression, generalized anxiety disorder (GAD), or other psychiatric condition	**Proceed to Step 3 on following page**
	□ Neuropathic pain □ Fibromyalgia	**Proceed to Step 4 on following page**
	□ Other (specify):	**Coverage not approved**

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Step 3 — **Depression, generalized anxiety disorder (GAD), or other psychiatric condition**

1. The Step 1 agents are: **1) venlafaxine** [Effexor, Effexor XR]; **2) SSRIs** [**selective serotonin reuptake inhibitors**, citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline]; **3) nefazodone, trazodone**; **4) bupropion HCL** [Wellbutrin]; **5) mirtazapine** [Remeron]; **6) TCAs** [**tricyclic antidepressants**: amitriptyline (Elavil), desipramine (Norpramin), doxepin (Sinequan), imipramine (Tofranil), nortriptyline (Pamelor), protriptyline (Vivactil)]; and, **7) MAO inhibitors** [monoamine oxidase inhibitors: Emsam, Marplan, Nardil, Parnate].	**Proceed to question 2**	
2. Are ALL of the Step 1 agents listed above contraindicated in this patient?	Yes **Sign and date below**	No Proceed to Question 3
3. Has the patient previously responded to Cymbalta and changing to a Step 1 agent would incur unacceptable risk?	Yes **Sign and date below**	No Proceed to Question 4
4. Has the patient tried one of the Step 1 agents and experienced adverse effects?	Yes Document agent(s) in **6**	No Proceed to Question 5
5. Has the patient had an adequate therapeutic trial with one of the Step 1 agents and the use resulted in therapeutic failure?	Yes Document agent(s) in **6**	No **Coverage not approved**
6. DOCUMENT the Step 1 agents(s) that has been tried, then sign and date below:		

Step 4 — **Neuropathic pain, Fibromyalgia**

1. The Step 1 agents are: 1) venlafaxine [Effexor, Effexor XR]**; 2) gabapentin** [Neurontin]**; 3) TCAs** [**tricyclic antidepressants:** amitriptyline (Elavil), desipramine (Norpramin), doxepin (Sinequan), imipramine (Tofranil), nortriptyline (Pamelor), protriptyline (Vivactil)]**;** and, **4) cyclobenzaprine.**	**Proceed to question 2**	
2. Are ALL of the Step 1 agents listed above contraindicated in this patient?	Yes **Sign and date below**	No Proceed to Question 3
3. Has the patient previously responded to Cymbalta and changing to a Step 1 agent would incur unacceptable risk?	Yes **Sign and date below**	No Proceed to Question 4
4. Has the patient tried one of the Step 1 agents and experienced adverse effects?	Yes Document agent(s) in **6**	No Proceed to Question 5
5. Has the patient had an adequate therapeutic trial with one of the Step 1 agents and the use resulted in therapeutic failure?	Yes Document agent(s) in **6**	No **Coverage not approved**
6. DOCUMENT the Step 1 agents(s) that has been tried, then sign and date below:		

Step 5

I certify the above is true to the best of my knowledge.
Please sign and date:

Prescriber signature _____ Date _____

[18 April 2012]